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(71) Applicant: MOUNTPELIER INVESTMENTS, S.A.
Kastanienhof Pflugstrasse 10
FL-9490 Vaduz(LI)

(72) Inventor: Fiddian-Green, Richard G.
127 Brigham Hill Road
North Grafton, Massachusetts 01536(US)

(74) Representative: Williams, Trevor John et al
J.A. KEMP & CO. 14 South Square Gray's Inn
London WC1R 5LX(GB)

(54) Catheter.

(57) Medical treatment apparatus for sustaining the vitality of an organ in the gastrointestinal tract by catheterisation including improvements in catheter placement, ischemia detection, and oxygenation. A disclosed embodiment of the catheter has magnetically responsive structure at its top and a device for aid in placement of the catheter has an electromagnet cooperative with the magnetic tip. The catheter (170) has a lumen (178) through its length to receive a removable guide wire (174).

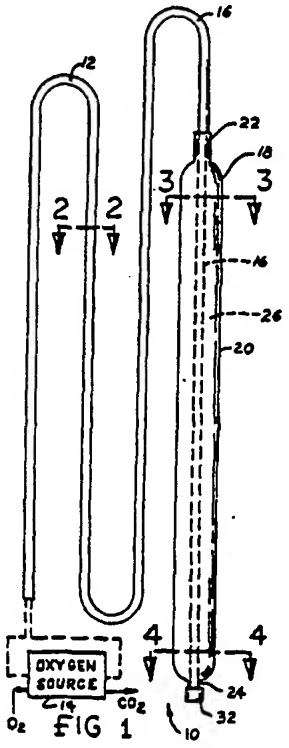

FIG 1

EP 0 422 689 A2

CATHETER

This invention relates generally to medical treatment apparatus. More specifically, it is concerned with a catheter for use in sustaining vitality of an organ in the gastrointestinal tract by catheterisation.

The nature of human anatomy is such that each individual organ's vitality is sustained by the circulation of blood through the organ's vascular system. Each organ's vascular system is, of course, a part of the body's larger cardiovascular system.

For any of various reasons the circulation, and hence oxygen delivery, to any given organ may become insufficient to sustain the full vitality of that organ. For example, partial occlusion of an artery may reduce blood flow to a point where the oxygen supply is insufficient. An occlusion, whether full or partial, may be due entirely to naturally occurring phenomenon or it may be in consequence of certain procedures. Regardless of the cause, reduced oxygen delivery can have potentially devastating effects on a patient.

As another example, surgical procedures, possibly not even directly related to a particular organ, may have an effect on the organ. For instance, in the cause of certain vascular surgery procedures, it may be necessary to interrupt the blood flow to a given organ or organs during the course of procedures. External blood pumps may be used to supply the organ or organs during these procedures or else the procedures must be performed with sufficient rapidity that the temporary interruption of circulation to an organ will not produce grave consequences.

The present invention is in one respect directed to a catheter for use in apparatus for sustaining vitality of an internal organ in situations such as these, particularly with reference to gastrointestinal organs. With such apparatus it is unnecessary to utilise external devices, such as blood pumps, in association with the vascular system. Apparatus using the catheter can be used at any desired time, for example, pre-operatively, during an operation or post-operatively.

The apparatus does not directly to involve the cardiovascular system. Rather, the catheter is introduced into an organ of interest. The catheter comprises a tube having a walled chamber structure at one end. The catheter is introduced to dispose the chamber structure against the lumen of the organ of interest. The material of the chamber is on which is freely permeable to gas but poorly permeable to liquid. The tube contains a conduit for delivering fluid to th chamber.

The catheter has a dual capability - 1. to monitor incipient ischemia in the organ of interest and 2. to oxygenate the organ. When the organ is being monitored for ischemia, perfusion fluid is introduced and subsequently extracted to obtain a CO_2 sample from the lumen of the organ. the pCO_2 measurement is utilised to calculate the organ's pH. The calculated pH can be used as an indicator of incipient ischemia.

When the catheter is being used for organ oxygenation, oxygen is perfused through the chamber via the tube from an external source. The external source may comprise any suitable means to create an oxygen partial pressure gradient between the interior of the chamber and the lumen of the organ whereby oxygen can diffuse through the wall of the chamber and into the organ. Carbon dioxide gas generated by the organ can also diffuse through the wall of the chamber to be conveyed back through the tube for removal.

In the disclosed embodiment, the chamber and tube are so constructed and arranged as to create an axial flow along the interior of the wall of the chamber along substantially the full length of the chamber. This promotes the maximum area availability for delivering oxygen to an organ, particularly in the case where the organ is in the gastrointestinal tract. The diameter of the chamber is less than that of the organ so that the catheter does not block passage through the organ. It is also contemplated that there may be used agents, such as vasodilator may be used to enhance oxygenation locally and blood and/or blood substitutes may be used for oxygen-bearing purposes.

The present invention is divided from EP-A-232 968 which relates to catheter placement through the use of an auxiliary placement device in association with the catheter. An endoscope may be used as the auxiliary placement device. A disclosed embodiment of catheter has magnetically responsive structure at its tip, and the auxiliary device has an electromagnet which is cooperatively associated with the magnetic tip. The auxiliary device is operated to maintain electromagnetic attraction of the magnetic tip structure during an initial phase of the placement process. The auxiliary device is relatively stiffer than the catheter and is used to force the catheter tip past the pylorus when the catheter is introduced into the intestines from the stomach. Thereafter a separate external magnet is used to attract the catheter tip, the electromagnet is deenergised and the auxiliary device withdrawn. Final placement of the catheter is attained through manipulation of the external magnet.

The present invention will be further described ith reference to the accompanying drawings, in

which:-

Figure 1 is a view, partly schematic, illustrating apparatus which may use the catheter of the present invention.

Figures 2, 3 and 4 are enlarged transverse cross-sectional views taken in the direction of arrows 2-2, 3-3 and 4-4 respectively in Figure 1.

Figure 5 is a view, partly schematic, illustrating another form of apparatus which may use the catheter of the present invention.

Figure 6 is a view similar to Figure 5 showing a further modification.

Figures 7, 8, 9 and 10 are respective views illustrating representative method steps in use of the apparatus.

Figure 11 shows another form of catheter.

Figures 12 to 16 illustrate another sequence of method steps using a further form of catheter, this catheter being in accordance with the invention.

Figure 1 illustrates an exemplary embodiment of apparatus 10 for practice of organ oxygenation. Apparatus 10 comprises a catheter designated by the general reference numeral 11. Associated with catheter 11 is any suitable oxygen source designated by the general reference numeral 14.

Catheter 12 comprises a tube 16 on the distal end of which is disposed a walled chamber 18. The opposite proximal end of tube 12 is adapted for connection with apparatus 14.

Chamber 18 is provided by a tubular element having a nominal diameter greater than that of tube 16. Figure 1 illustrates a representative shape but the invention is not limited to the particular shape or proportions illustrated. The tubular element 20 constitutes a membrane which forms chamber 15 and is fitted over the distal end of tube 16. The opposite axial ends of element 20 are closed onto the outside of tube 16 as at 22 and 24. In this way, the chamber 18 defines an annular space 16 around the outside of tube 16.

Tube 16 is a soft pliable material, silicone for example, which has a circular cross-sectional shape. Tube 16 is provided with a pair of axially extending conduits, or passages, 28 and 30 respectively, these extend the full length of the tube and the catheter includes any suitable closure means, for example an end closure element 32 to close off the distal end of the tube for the purpose of closing conduits 28 and 30 at that end.

Conduits 28 and 30 are communicated with the interior chamber space 26 by means of respective apertures 34 and 36 as shown in Figs. 4 and 3 respectively. Each aperture is provid d as a transversely extending hole from the exterior of the wall of tube 16 to intercept the corresponding conduit as shown in the drawing figures.

In use oxygen is introduced into one of the two conduits and conveyed through tube 16 to exit the tube at the corr sponding aperture into chamber space 26. The interior of the chamber space is thereby perfused with oxygen. The opposite aperture provides for return conveyance of gases via the other conduit through tube 16.

Hence, if oxygen is introduced into conduit 28, it will flow through that conduit, exit via aperture 34 and pass into the far distal end of chamber space 26. The flow will continue axially through the annular chamber space 26 toward the proximal end of the chamber to enter aperture 36 and subsequently pass via conduit 30 back through tube 16.

If the direction of flow were to be reversed, flow through chamber space 26 would be distally, exiting tube 16 at aperture 36, passing axially through the chamber space to re-enter tube 16 at aperture 34 for return via tube 16.

The material of tube 20 is one which is freely permeable to gas but poorly permeable to liquid, so that tube 20 is a membrane. A suitable material is polydimethylsiloxane which is freely permeable to oxygen and carbon dioxide gases. The oxygen in the catheter chamber has a partial pressure so that oxygen can diffuse through the wall of the chamber 18.

In use, catheter 12 is introduced into a patient such that chamber 18 is placed against the lumen of the hollow internal organ of interest. The elongate shape illustrated in Fig. 1 is intended for placement in the gastrointestinal tract, particularly the intestines. The placement may be made preoperatively or intraoperatively, and the catheter may remain in place even into a postoperative period.

Apparatus 14 is of any suitable configuration which is capable of perfusing oxygen through tube 16 and chamber 18 at a suitable partial pressure. For example, the apparatus may comprise a standard hospital oxygen supply giving a pressure of 760 mm.Hg. It could also alternately comprise a pump which delivers oxygen-enriched fluid. For example, the fluid may be a saline solution which is pumped by the pump through the catheter, with provisions being made for oxygenating the saline solution prior to introduction into the catheter so that the fluid bears a dissolved oxygen gas at suitable partial pressure.

With the wall of chamber 18 being placed against the lumen of an internal organ, the flow of oxygen axially along the interior of the wall of tube 20 creates a condition whereby oxygen can diffuse through the wall of tube 20 and into the lumen of the organ. The diameter of chamber 26 is less than that of th organ so that the cath ter does not block flow through th tract. In this way, oxygen may continue to be supplied to th organ so as to sustain its vitality under conditions which otherwise might render the organ moribund. B cause the

organ will also generate carbon dioxide gas as a waste product, that waste gas can diffuse from the lumen through the wall of tube 20 and into th fluid which is being conveyed through chamber spac 26.

The carbon dioxide gas is conveyed from chamber space 26 with the exiting fluid flow which passes proximally through tube 16 to the proximal end. In this way not only is oxygen made available to the organ but a waste product from the organ is also removed.

Depending upon the degree of sophistication of apparatus 14 the carbon dioxide may be removed from the fluid and the fluid recirculated so as to form a closed system or otherwise the apparatus may be an open system in which the fluid which returns from tube 16 is discarded.

In order to sustain vitality of the intestine, the PO_2 of the oxygen introduced into chamber 26 must be high enough to create a certain gradient across the wall of the chamber and the lumen of the organ. In the lumen of a healthy intestine the PO_2 is about 100 mm.Hg. If the organ becomes ischemic, this figure drops to about 60 mm.Hg. Therefore, the PO_2 of the fluid delivered to the catheter should certainly exceed 100 mm.Hg. At the present time the use of 760 mm.Hg. oxygen gas as the sole fluid introduced into the catheter appears to be very effective. The return flow is merely exhausted.

The invention is also preferably practiced such that the material of tube 20 is not significantly stretched, or expanded, when in use, so that blockage of the passage through the tract may be avoided.

The material of tube 20 will be permeable to molecules having molecular weights of less than about 3000. Therefore, it is also possible to use the catheter to introduce drugs, nutrients, and/or other agents having molecular weights of less than about 3000.

Certain agents enhance the effectiveness of the procedure. For example it is possible to introduce a vasodialator via the catheter to enhance the local oxygenation. It is also contemplated that blood or blood substitutes could be used in an oxygen-bearing fluid to enhance the oxygen carrying capacity.

A significant advantage of use of the apparatus is that it is unnecessary to directly involve the circulatory system. This is different in principle from prior vascular oxygenation procedures which merely oxygenate the blood. Oxygen is made available directly to the lumen of the organ. The oxygen so delivered may be assistive of the current vascular flow, or it may be the sole source of oxygen.

The present disclosure illustrates apparatus in a form which is especially useful for th intestine.

The apparatus has been shown to provid for perfusion of oxygen through a hollow internal organ of the gastrointestinal tract indep ndently of the vascular system. The oxyg n so d livered may be assistive of current blood flow to the organ or it may be the sole source. While the apparatus may be used alone, it may also be practiced in conjunction with other procedures. The perfusion is accomplished with direct oxygen delivery to the lumen of the organ in a controlled manner without blockage of the tract.

There is the capability of selectively operating the catheter to monitor for incipient ischemia of the organ of interest and to oxygenate the organ. Briefly, when an organ is being monitored for incipient ischemia, aspirating fluid is introduced, equilibrated, and subsequently extracted to obtain a pCO_2 sample from the lumen of the organ. The pCO_2 measurement is utilized in calculating the organ's pH. Calculation of pH is performed using conventional procedures relating the pC02 measurement to the bicarbonate concentration in arterial blood. The pH measurement is used as an indicator of incipient ischemia.

Fig. 5 illustrates an exemplary apparatus 100 which includes a catheter 102 which is essentially like catheter 12 of Figs. 1-4. A detailed description of catheter 102 will therefore not be given.

A principal difference in the apparatus 100 versus apparatus 10 described in Figs. 1-4 involves equipment external of the catheter. This equipment in apparatus 100 provides for the dual capability of monitoring/oxygenating.

Apparatus 100 comprises in addition to the oxygen source 14, an aspirating fluid source 104. The two sources 14 and 104 are operatively coupled with catheter 102 by a valve mechanism, generally 106. Valve mechanism 106 comprises two separate valve devices 106a, 106b and each valve device has three ports and is selectively operable to at least two different positions. Preferably the two valve devices are connected to a common operator for ganged operation in unison.

In the position shown in Fig. 5 the valve devices 106a, 106b serve to connect oxygen source 14 to the catheter tube so that the same type of circuit exists as in Fig. 1. In this position oxygen perfusion fluid can pass through valve device 106a, and into the catheter. The return flow is via valve device 106b. This flow is depicted by the small arrows 107 for the entrance flow into the catheter and the arrows 108 for the exit flow from the catheter. At this time there are no flow paths from the aspirating fluid source 104 to the catheter, and accordingly oxygen perfuses the organ of interest to assist in sustaining its vitality.

When the two valve devices are operat d to a second position, the aspirating fluid source 104 is

connected to the catheter while the oxygen source 14 is disconnected. This is done for example by rotating the valving portions of the two valve devices 90° in the clockwise direction as viewed in Fig. 5. In this second position, flow from aspirating fluid source 104 passes through valve device 106a and into the catheter. The return flow from the catheter is through valve device 106b back to aspirating fluid source 104.

The purpose of introducing aspirating fluid into the catheter is to obtain a sanple of CO_2 gas generated by the organ of interest for the purpose of securing a pCO_2 measurement. There are various techniques for obtaining the pCO_2 measurement and one way is to introduce a certain amount of aspirating fluid into the walled catheter chamber and leaving it there for a sufficient amount of time to allow CO_2 gas to diffuse from the organ's lumen, through the permeable wall of the catheter chamber, and into the aspirating fluid and equilibrate. For example, 1/2 hour may be suitable in certain applications. The aspirating fluid is then withdrawn from the catheter and is subjected to analysis such as for example, by a conventional gas analyzer to measure the pCO_2.

A measurement of the bicarbonate concentration in arterial blood of the patient is also obtained, and these two measurements are then used to calculate the pH of the organ of interest. Such measurements may be taken at perlodic intervals and in this way a record of pH values can be established.

A certain change in pH is indicative of incipient ischemia, and therefore when such a potentially devastating condition is detected, the apparatus may then be operated to oxygenate the organ in an effort to counter the ischemic tendency. In this way apparatus 100 may be selectively used for its dual capability of monitoring/oxygenating.

Fig. 6 illustrates a feature which facilitates catheter placement. It is useful with both catheters 12, 102 and other forms of catheters as well. One of the major difficulties in successfully employing a gastrointestinal catheter is that of placement into the tract. In order for such a catheter to conform to the tract while creating as little discomfort as possible it is desirable that the catheter be a soft, pliable bio-compatible material, such as that described earlier. Unfortunately a soft, pliable elongate member is inherently difficult to place into the tract. Making the catheter stiffer for placement purposes is counterproductive to the need for having a soft, pliable construction. Therefore, the description with references to the Figures 6-10 relates to a solution to this problem.

The catheter is provided with a magnetic medium, for example on the tip end, as shown at 120 in Fig. 6 for catheter 12. A separate, elongate, auxiliary placement device 122 is utilized in association with the catheter and comprises an electromagnet 124 at the distal end which is adapted to be selectively energized from an external source at the proximal end. The external source is shown to comprise a battery 126 connected through a series on-off switch 128 to electro-magnet 124. When switch 128 is closed, the electro-magnet is energized, and when the switch is open, the electromagnet is de-energized.

The elongate device 122 comprises an elongate body 130 of relatively greater rigidity than the catheter itself. Preferably the conductive wires 132, 134 leading to the electro-magnet are embedded within this body, as is the electro-magnet. The external surface of the body is preferably smooth and bio-compatible

Placement is accomplished by placing the electro-magnet adjacent the tipped end of the catheter, and energizing the electromagnet to unite the catheter and the placement device at their distal ends. They are then introduced into a patient, for example via nasal introduction.

Fig. 7 shows the catheter and placement device having been passed through the esophagus 140 and into the stomach 142. The placement device has sufficient rigidity so that it can be forced into the tract, and by virtue of magnetic coupling with the catheter, pull the catheter along with it.

A particular difficulty in catheter placement is typically encountered at the pylorus 144. The auxiliary placement device can be used to force the pylorus open so that both it and the catheter pass through the pylorus and into the small intestine 146, This is shown in Fig. 8. Once the pylorus his been passed, the next problem encountered is to successfully withdraw only the electro-magnet. Since the pylorus keeps tending to reject the intruding apparatus, a counter-force is inherently being applied to the apparatus. A further feature is shown in Fig. 9 involves placing a strong magnet 148 externally of the intestine at the vicinity of the catheter's tip end. Fig. 9 shows magnet 148 extraoperatively acting through the patient's abdomen 149. This external magnet has sufficient strength to hold the tip of the catheter in place while the electro-magnet 124 is de-energized and the auxiliary device 122 is then withdrawn. Because of its nature electro-magnet 124 will not be significantly attracted to the external magnet when de-energized. Yet, the strength of the external magnet will hold the tip end of the catheter jn place so that upon withdrawal of the auxiliary d vic , only the soft pliable catheter is left in place.

If the cathet r is in a suitable position by virtu of its placement by device 122, then no further manipulation of the external magnet 148 need be

done. It is contemplated however that further catheter placement may be required, and this can be done by a suitable manipulation of magnet 148 to move the catheter to the desired placement site. This further manipulation is shown by Fig. 10.

It can therefore be appreciated that significant facility is given to the attending physician in placement of a catheter. Once the catheter has been placed, procedures such as those described above with reference to Figs. 1-4 and Fig. 5 may be conducted when catheters of those types are employed. The placement procedure is however applicable to other types of catheters, and other devices, duodenal feeding tubes for example. Advantageously, the auxiliary placement device 122 could be a fibro-optic endoscope designed to contain the electro-magnet and wires.

Fig. 11 portrays another form of apparatus 160 which is similar to the apparatus of Fig. 6. Apparatus 160 comprises a catheter 162 which corresponds to catheter 12 but is disposed within a hollow tubular placement device 164 corresponding to placement device 122. Fig. 11 is of a somewhat schematic nature for purposes of illustrating this alternate configuration. The electro-magnet 124 is a coil which is disposed at the distal end of the tubular placement device 164. The lead wires from the electro-magnet extend through the placement device. The catheter 162 contains a magnetic tip end 120. The same steps described earlier are used to effect placement of catheter 162 by placement device 164.

Figs. 12-16 show schematically a sequence of steps for catheter placement but using a modified form of apparatus embodying the present invention. In Figure 12 an endoscope 170 has a longitudinal passage 172 containing a guidewire 174. The combination of 170 and 174 is introduced into the patient, as in the same manner described above.

Upon having achieved a desired amount of introduction (the distal end having passed the pylorus for example), the endoscope 170 is withdrawn while the guidewire 174 remains in place. (See Fig. 13.) It is contemplated that endoscope withdrawal can be accomplished by an external manipulation so that the guidewire need not necessarily be made magnetically responsive; however, as an aid to assuring that the guidewire remains in place, or at least a portion of it, such as the distal end, can be magnetically responsive so that the procedures described earlier can be used to hold the guidewire in place while endoscope 170 is withdrawn.

After the ndoscope has been withdrawn, a catheter 176 essentially like catheter 12 is introduced (see Fig. 14). Catheter 176 may be like catheter 12, but includes a passage 178 which allows it to be guided along the in-place guidewir 174. The illustrated embodiment shows the passage 178 as being formed as its own lumen in the wall of the tube 16 so that there is no interference with the coop rative relationship of the other parts of the catheter.

When desired catheter placement has been obtained (see Fig. 15), guidewire 174 may be withdrawn leaving the catheter alone in place (Fig. 16). The catheter tip is magnetically responsive so that it can either be held in place as the guidewire is withdrawn and/or used for further catheter placement by manipulation of magnet 148. By suitable design, the external magnet 148 may result in a larger holding force being applied to the magnetically responsive catheter tip than to the guidewire, assuming the latter is magnetically responsive, whereby the catheter will remain in situs as the guidewire is withdrawn despite some magnetic force acting on the guidewire.

Figs. 11-16 have described different apparatus and procedures for placement. However both catheters 162, 176 embody the same principles as catheter 12 whereby after placement the oxygenation and/or monitoring procedures described in connection with catheter 12 can be performed.

The foregoing description has disclosed principles of use of the invention, with reference to certain to certain embodiments and steps. Principles may be practiced in embodiments and steps other than the apparatus and steps specifically shown and described. The catheters may be introduced either through the anus into the colon or nasally in the manner described and illustrated in Figs. 7-10. Certain steps may be performed extra-operatively or intra-operatively, and one example of an intra-operative step would be the use of an external magnet against the outer aspect of the intestines to facilitate catheter placement during a surgical procedure. Figs. 9 and 10 portray extra-operative placement. The external magnet 148 can be a permanent magnetized piece of magnetic material, or it can be an electro-magnet which is selectively energizable. The illustrated configuration of the magnetic material on the catheter tip and the use of a single electro-magnet on the auxiliary placement device are also considered to be representative. It is possible to have multiple magnetic media on the catheter, for example at different locations, and to endow the auxiliary placement apparatus with more than one electro-magnet. While the distal end of the catheter is deemed to be the most appropriate location for the magnetic material, it will be appreciated that other placement locations may be used. Also the magnetically responsive medium on the catheter could be a magnet or an electro-magnet instead of merely a magnetically responsive piec of material.

Claims

1. A catheter comprising a soft pliable tube (12) for introduction into the gastrointestinal tract, a walled sampling chamber (26) on the tube comprising a wall (20) of material which is freely permeable to gas but poorly permeable to liquids, the sampling chamber being in communication with said tube so that fluid can be introduced into said chamber via said tube, a magnetically responsive means on said catheter providing for electromagnetic attraction with an electromagnetic influence which is external to the catheter, and a separate lumen (178) through the catheter for guiding of the catheter (170) on a guidewire (174).

2. A catheter according to claim 1, wherein a removable guide wire (174) is threaded through said separate lumen (178).

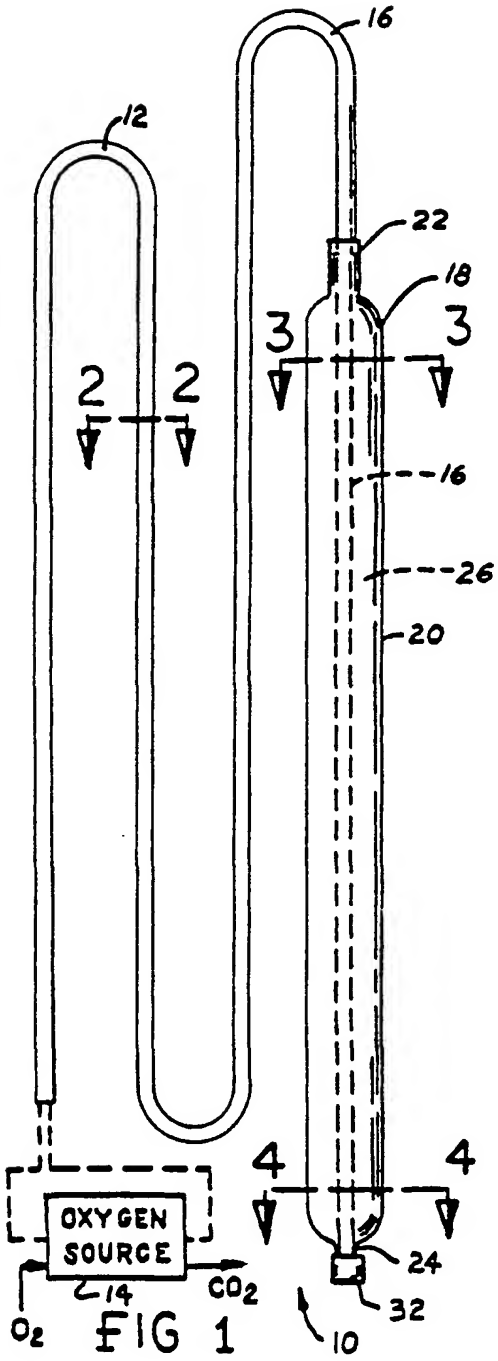

FIG 1

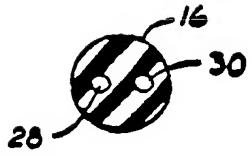

FIG 2

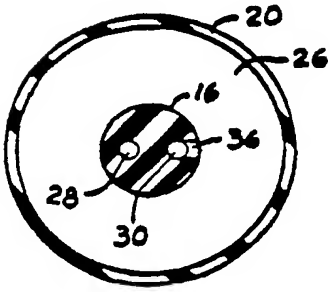

FIG 3

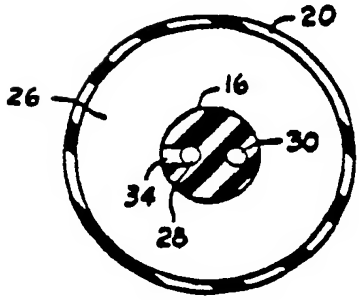

FIG 4

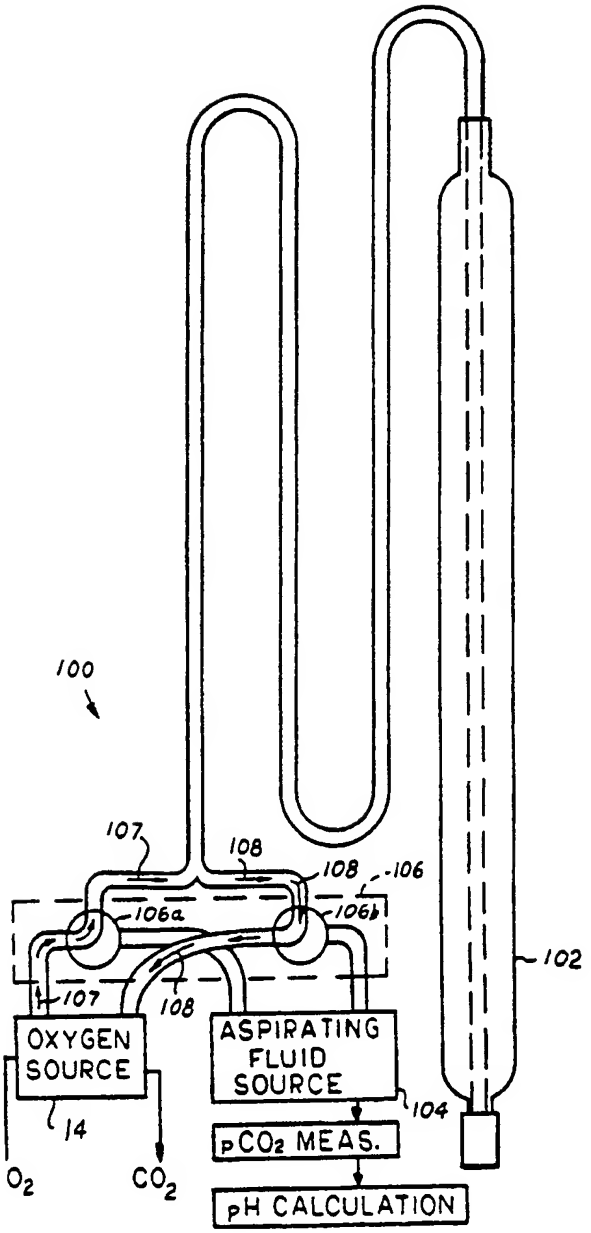
100
107
108
108
106
106a
106b
102
107
108
OXYGEN SOURCE
14
ASPIRATING FLUID SOURCE
104
pCO2 MEAS.
pH CALCULATION
O2
CO2

FIG. 5

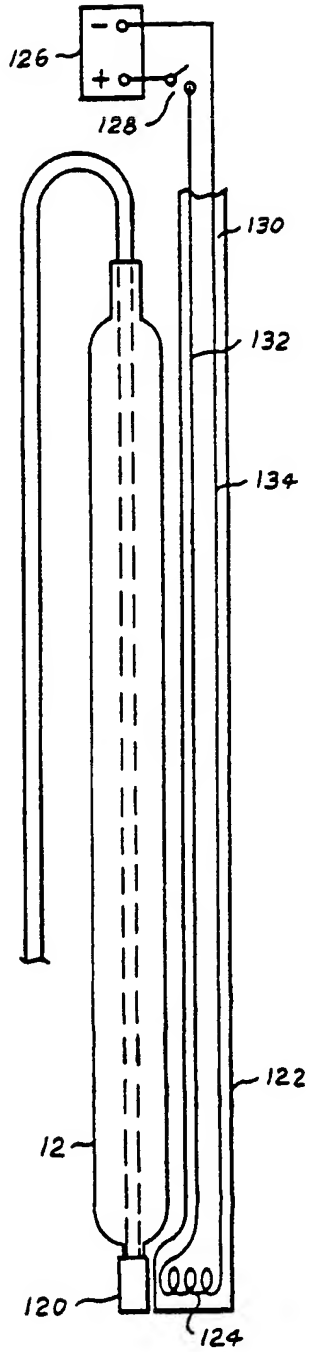
126
128
130
132
134
122
12
120
124

FIG. 6

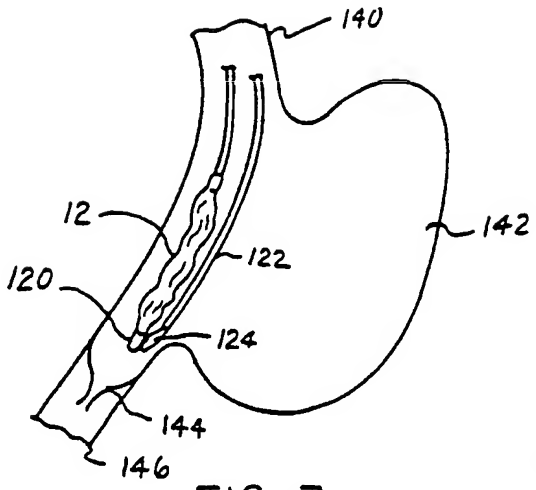

FIG. 7

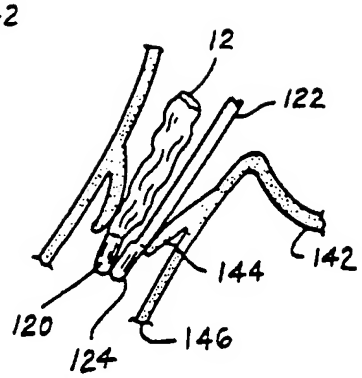

FIG 8

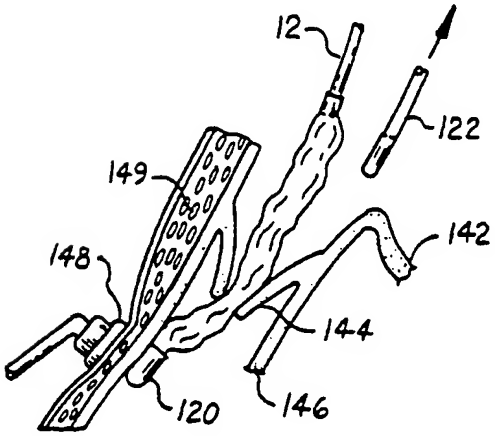

FIG 9

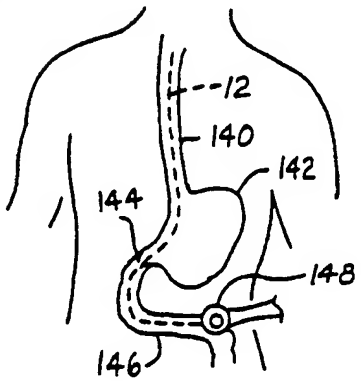

FIG 10

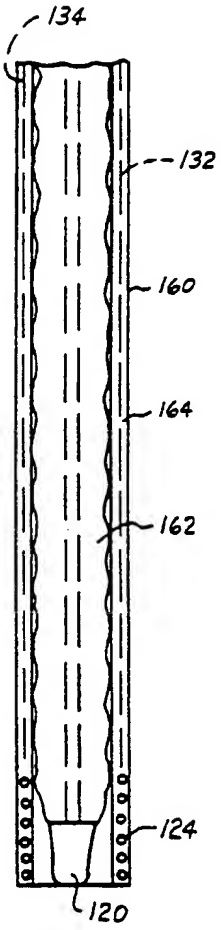

FIG. 11

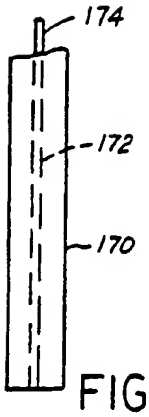

FIG. 12

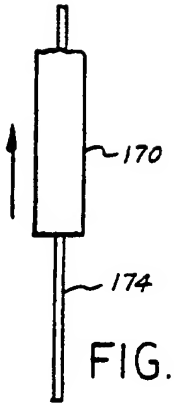

FIG. 13

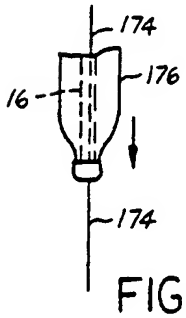

FIG. 14

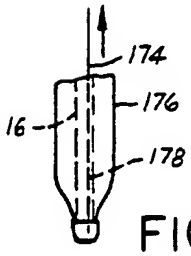

FIG. 15

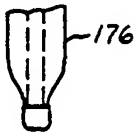

FIG. 16